

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

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SYSTEM PRODUCTS LIABILITY	:
LITIGATION	:
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**PLAINTIFFS' STEERING COMMITTEE'S REPLY MEMORANDUM IN SUPPORT OF
ITS MOTION TO
COMPEL PRODUCTION OF SALES REPRESENTATIVE FILES**

In further support of Plaintiffs' Motion to Compel Production of Sales Representative Files, Plaintiffs, through Plaintiffs' Steering Committee, state as follows:

ARGUMENT

I. Defendant Fails to Justify a Deviation from the Rule that Relevant Information is Generally Discoverable

1. The Sales Representatives' Documents are Relevant and Discoverable

Defendant claims that Plaintiffs have “failed to find the ‘smoking gun’ in the custodial file [sic] for the 129 sales representatives that actually had contact with Plaintiffs’ treating physicians” and therefore “ask this Court to authorize a true fishing expedition....” Def.’s Brf. at 1. As an initial matter, Defendant’s reference to the production of 129 custodial files is misleading. As explained in Plaintiffs’ initial brief—and as will be explained further in a motion for spoliation—Defendant has failed to provide a meaningful production of documents from many of the sales representatives in the bellwether cases. Additionally, Defendant’s cliché cry that Plaintiffs are embarking upon a “fishing expedition” only demonstrates the knee-jerk nature of its response brief and totally ignores the content and detail of Plaintiffs’ Motion. Indeed,

Plaintiffs' initial brief laid out exactly what types of documents the sales representatives might have, why they might have them, and why those documents would be relevant to Plaintiffs' claims. Plaintiffs have gone above and beyond what is required on a motion to compel.¹

As Plaintiffs discuss in great length in their initial brief, Defendant's sales representatives are likely to possess relevant and discoverable information evidencing communications with clients, complaints about adverse events, training materials, product information, and the risks and benefits represented (to physicians) to be associated with the products. *See*, Pltfs.' Brf. at 4-7. This information is directly relevant to Plaintiffs' failure to warn and fraud claims, along with Plaintiffs' entitlement to punitive damages. *Id.* Additionally, obtaining this information from non-bellwether sales representatives allows Plaintiffs to establish company-wide policies that relate to their negligence, failure to train, failure to warn (and learned intermediary doctrine), and punitive damages arguments, among others. *Id.* Finally, this information is vital to allow Plaintiffs the opportunity to rebut (on cross-examination) any argument that a sales representative in one of the bellwether cases was a rogue actor or did not comply with company norms. *Id.* Defendant completely fails to address these arguments in its response brief.²

Instead, Defendant wastes much of its brief attempting to distinguish or contrast the interaction between sales representatives and physicians in the medical device industry with that of the pharmaceutical industry. Defendant apparently does so in an attempt to argue that the

¹ In a footnote, Defendant accuses Plaintiffs of "avoid[ing] the legal standard because it is clear that the Federal Rules of Civil Procedure and case law do not support the unbridled fishing expedition that Plaintiffs propose." Def.'s Brf. at 2, fn. 2. Ethicon then goes on to cite boilerplate law standing for the basic principle that limiting discovery is within the discretion of the Court—but provides absolutely no discussion of the facts of those cases to the current discovery dispute. Plaintiffs did not "avoid" any legal standard. Why would they? The "legal standard" is generally that Plaintiffs are entitled "...to obtain discovery regarding a non-privileged matter that is relevant to any party's claim or defense...." Rule 26(b)(1). Plaintiffs do not dispute that Rule 26 provides this Court the discretion to limit discovery where abusive—but it is Defendant's burden to establish that the relevant information in its possession should not be produced. *Minter v. Wells Fargo Bank, N.A.*, 258 F.R.D. 118, 124 (D.Md.2009).

² The closest Defendant comes to responding to these arguments is to simply assert: "none of this purported conduct would in any way relate to any of the bellwether Plaintiffs that are set for trial." Def.'s Brf. at 7. This strange comment is not explained or supported by any citation to law. Plaintiffs' ability to establish, negligence, failure to warn or test, and fraud are clearly relevant to any trial.

sales representatives' files would not contain relevant, discoverable, and admissible evidence. This entire argument is simply misdirection.

For example, Defendant attempts to limit the discussion to just "call notes" (according to its own definition of that term), and then argues that "call notes" would not be found in the sales representatives' files because Defendant's "medical device sales representatives have not been directed to keep call notes." Def.'s Brf. at 7. First, the fact that documentation of a conversation is not mandated by regulation or company policy does not establish that such relevant evidence does not exist—nor does it excuse a party from having to produce it if it does exist.³ Additionally, Plaintiffs did not limit their document request to only the "call notes" discussed by Defendant. In fact, Plaintiffs' brief specifically explained that: "the detailer's files contain so much more than just call notes, such as training materials and additional product information."⁴ Pltfs.' Brf. at 2. All of those documents are relevant and discoverable.

Defendant goes on to claim that "[m]edical devices are not sold to doctors, but to facilities at which surgeries take place" (Def.'s Brf. at 5). But that fact, even if accepted as true, is irrelevant because the evidence in this litigation establishes that Defendant's sales representatives personally interact with surgeons. *See e.g.*, Pltfs.' Brf. at Ex. 5, Parisi deposition 6-6-2013 at 215; and Ex. 6, Depo Ex. T-1065 (previously provided *in camera* as exhibits to Plaintiffs' Memorandum in Support of its Motion to Compel Production of Sales Representative Files). Any record of those conversations—regardless of whether it relates to the actual purchase/sale of a product—is discoverable.

³ Additionally, as mentioned in Plaintiffs' initial brief, what sales representatives write in their own personal notes about the content of their communications with physicians is very likely to much more accurately describe their communications with physicians than any other source of information—such as mandated records and documentation.

⁴ Common sense suggests that company marketing messages are relayed, in large part, through sales representatives.

Defendant also claims that “tracking the identity and number of people with which the medical device sales representative interacts...is not required for business purposes.” Def.’s Brf. at 6. Again, even if accepted as true, the fact that Defendant does not track the interactions of its sales representatives does nothing to negate the fact that any record of those interactions⁵ would be relevant and discoverable.

Finally, Defendant attempts to avoid the fact that its sales representatives’ communications could evidence knowledge of adverse events by stating: “the sources of Ethicon’s knowledge of adverse events are found in the source materials for the adverse event reports—which have been produced.” Def.’s Brf. at 7. While those adverse event reports do evidence knowledge of some adverse events, Ethicon’s “knowledge” or “notice” of adverse events is not limited to the events that it chose to report, but also includes any events described in the records of its employees (sales representatives)—which have not been produced.

In short, Defendant’s arguments that the medical device and pharmaceutical industries “are different in how they are regulated and how they function” (Def.’s Brf. at 5) do not change the fact that the sales representatives are in possession of relevant and discoverable documents—however Defendant wants to label, describe or categorize them.

2. PTO #41 Does Not Limit or Preclude General Discovery in this MDL

Defendant seems to at least infer (if not assert) that PTO #41 limits Plaintiffs to requesting the production of custodial files from only the sales representatives “who actually called on bellwether Plaintiffs’ treating physicians.” Def.’s Brf. at 1. That is simply not the case. PTO #41 has absolutely no bearing or preclusive effect on the discovery that Plaintiffs seek. Yes, Plaintiffs and Defendant did negotiate the disclosures required by the PTO #41 (the

⁵ Contrary to its own assertions, in its brief, even Defendant is forced to recognize the likelihood of relevant “record[s] of meetings between sales representatives and physicians.” Def.’s Brf. at 6.

Defendant's Fact Sheet) for each of the discovery pool cases; but PTO #41 only regulates the initial disclosures necessary in each of the bellwether cases. There was no agreement to limit general discovery or otherwise prevent Plaintiffs from requesting (and obtaining) relevant information regarding other sales representatives.

Moreover, PTO #41 was negotiated last winter, at a time when Plaintiffs could not possibly have expected the pervasive problems with Defendant's production of its sales representatives' files in the bellwether cases.⁶ Even if the entry of PTO #41 did effect the scope of general discovery allowed to the Plaintiffs—which it didn't—production of additional sales representatives' files is now necessary due to Defendant's lack of preservation and production of usable information from the files of the sales representatives in the bellwether cases.⁷

3. Defendant has Not Demonstrated Undue Burden and Lack of “Proportionality”

Defendant cites to case law holding that a court can balance the need for discovery “against the yardstick of proportionality.” Def.'s Brf. at 8-9. Plaintiffs do not contest that general rule. However, while Defendant includes a citation to the factors to be considered under Rule 26(b)(2)(C)(iii) (*i.e.* likely benefit, needs of the case, amount in controversy, parties' resources, importance of issues at stake, and importance of discovery in resolving issues), Defendant does not bother to discuss or apply those factors. Instead, Defendant simply recounts the amount of *other* discovery that has been taken in this MDL. The fact that Defendant has already produced a significant amount of other documents is to be expected in this type of litigation. More importantly, it is of no consequence to this Motion.

⁶ Defendant then claims that it “has complied with [PTO #41].” Def.'s Brf. at 2. However, Defendant later qualifies that statement by stating: “...responsive materials, *to the extent that they are available*, were collected and produced for approximately 130 sales representatives.” *Id.* at 9 (*italics added*). Defendant's qualification regarding the completeness of its production is telling.

⁷ By denying Plaintiffs' general production of sales representative documents, this Court would prejudice the Bellwether Plaintiffs for circumstances beyond their control and in complete control of the Defendant, as will more fully be discussed in Plaintiffs' motion for spoliation.

An application of the Rule 26 factors demonstrates that discovery of the sales representatives' files should not be precluded. First, Plaintiffs discussed the factual and legal relevance ("likely benefit" and "need") for the sales representatives' documents at length in their Motion. In short: the information that is likely to be found relates directly to Plaintiffs' claims and Defendant's defenses. Those two factors ("benefit" and "need") are further established by the fact that Defendant has not produce sufficient documents and files for many of the sales representatives in the bellwether cases. Second, this MDL involves the claims of tens of thousands of women who were seriously injured by Defendant's products; as such, both the "amount in controversy" and "importance of issues" factors clearly weigh in favor of compelling the discovery. Finally, while Defendant claims financial hardship will result from the granting of this Motion, the fact remains that Defendant is a large corporation with ample resources to collect and produce the documents requested. As such, the factors to be weighed by the Court under Rule 26 do not support a deviation from the general rule that Plaintiffs are entitled to the relevant information in the opposing party's possession. *See*, Fed. R. Civ. P. 26.

Plaintiffs have already demonstrated their willingness to take steps to lessen any alleged burden by proposing a rolling production of sales representatives' files. Defendant's response brief all but ignores the reasonableness of Plaintiffs' offer of compromise—other than to simply declare without justification that it is "unreasonable" in a footnote. Def.'s Brf. at 2, fn. 1. The 100 sales representatives⁸ that Plaintiffs propose selecting (at random) for an initial production of files would all have called upon doctors who treated Plaintiffs in this litigation. As Defendant has neither stated nor demonstrated a willingness to settle these non-bellwether cases, it can only be assumed that these files will eventually have to be collected and produced in the individual

⁸ As stated in Plaintiffs' initial brief, at one point Plaintiffs lowered this proposed number of sales representatives' files to only 50 a month. Pltfs.' Brf. at 3, fn. 3.

Plaintiff's cases, anyway. As such, there is really no *additional* burden being placed on Defendant by Plaintiffs' proposed compromise—it was already going to have to produce these files before any of the cases could be tried.

II. Defendant's Request for Cost-Shifting is Not Justified

Defendant requests that, should the Court compel production of sales representatives' files, the cost of that production be shifted to Plaintiffs on the grounds that it is “additional, duplicative and irrelevant discovery.” Def.'s Brf. at 12. As explained above, this discovery is not “additional or duplicative” because: (1) Defendant would have to produce this information in each of the individual cases; and (2) Defendant's lack of preservation and production of documents in the bellwether cases. Likewise, as referenced above and further explained in Plaintiffs' initial brief, this information is clearly not “irrelevant” because it relates directly to the claims and defenses in this litigation. As such, there is no justification for departing from the general rule that “the responding party must bear the expense of complying with discovery requests.” *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340 (1978).

Defendant does not cite to one single case from this Circuit in support of its suggestion that the production of clearly relevant documents should be shifted to the Plaintiffs in this case. Moreover, Defendant does not even propose (or apply) any test that this Court should apply when determining whether cost shifting is appropriate. That failure alone should warrant the denial of Defendant's request.

This Court has previously addressed and denied a similar request for cost-shifting by Defendant. In PTO #68, the Court recognized that different courts have used different tests; however, the Court agreed with the District Court of Maryland in *Thompson v. U.S. Dept. of Housing and Urban Development*, 219 F.R.D. 93 (D.MD. 2003), stating “the undersigned agrees

with the *Thompson* court that a fair cost-shifting analysis can be achieved by applying the factors found in Rule 26(b)(2)(C).” PTO #68.⁹ Similar to the result of this Court’s analysis in PTO #68, an application of these factors demonstrates that cost-shifting is also inappropriate in this situation.

1. Whether the discovery sought is unreasonably cumulative or duplicative:

Here, there can be no claim that the discovery is cumulative or duplicative. Indeed, it is Defendant’s inability to produce similar documents in the bellwether cases that, in part, necessitates the production of other sales representatives’ files. Additionally, the cumulative nature of these documents cannot yet be determined. As this Court stated in PTO #68: “It plainly is too early in the collection process to determine with any certainty the likelihood that future productions of regulatory documents will be cumulative and duplicative.” *Id.*

2. Whether the information sought is obtainable from some other more convenient, less burdensome or inexpensive source:

Defendant’s sales representatives are likely the only individuals who could be in possession of this information. Moreover, Defendant’s failure to preserve and produce similar information in bellwether cases further establishes a need for the production of the sales representatives files from non-bellwether cases.

3. Whether the party seeking the information already has had adequate opportunity to obtain the information:

Plaintiffs have had absolutely no prior opportunity to obtain the Defendant’s sales representatives’ files.

⁹ The factors in Rule 26(b)(2) include: “[W]hether the discovery sought is unreasonably cumulative or duplicative; whether the information sought is obtainable from some other more convenient, less burdensome or inexpensive source; whether the party seeking the information already has had adequate opportunity to obtain the information; and whether the burden or expense of the proposed discovery outweighs its likely benefit, taking into consideration the following: the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake in the litigation and of the discovery sought to the resolution of the issues.” *Id.*

4. Whether the burden or expense of the proposed discovery outweighs its likely benefit, taking into consideration the following: the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake in the litigation and of the discovery sought to the resolution of the issues:

When considering this factor in relation to Defendant's assertion that the cost of its collection of OUS documents (also estimated by Defendant to be in between \$500,000 and \$1M) should be shifted to Plaintiffs, this Court opined:

This multidistrict litigation includes over ten thousand plaintiffs, claiming to be permanently injured by Ethicon's mesh products. In cases involving Ethicon's pelvic mesh that have gone to trial, the Plaintiffs' verdicts have been in the millions of dollars. Accordingly, the amount in controversy far exceeds the projected costs of producing the regulatory documents, even when considering the costs already incurred by Ethicon in the course of discovery. Moreover, Ethicon is part of a multibillion dollar family of companies; therefore, absorbing these discovery costs should not financially cripple Ethicon. In addition, the issues at stake are not only important to the thousands of plaintiffs that have been treated with Ethicon's mesh, but may have broad public impact in the way that similar products are designed, manufactured, tested, marketed, sold, and implanted.

That same reasoning is applicable to Defendant's current request for cost-shifting.

Moreover, as stated above, Plaintiffs' proposed compromise only requests the files of sales representatives who called upon physicians in non-bellwether plaintiffs' cases. As such, the relevant sales representatives' files would have to be produced in each of these individual cases as a matter of course. Plaintiffs simply request that these files be produced now, during the general discovery and the bellwether process—where they will further the interests of all of the cases—as opposed to later, during the case specific discovery for each of these individual cases.

CONCLUSION

For any of the foregoing reasons, Plaintiffs respectfully request that the Court order Defendant to: (a) produce all custodial files of sales representatives calling on physicians treating bellwether plaintiffs, as agreed to already; (b) begin a rolling product of the custodial files of a minimum of 100 sales representatives (or 50, as explained above) per month, with Plaintiffs

choosing the representatives from among those already involved in cases in this litigation; and
(c) to otherwise fully and completely respond to Requests for Production numbers 98-104, 106,
108, 109-110. Plaintiffs further request all other relief to which they are entitled.

Dated: September 20, 2013

Respectfully submitted,

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IN RE ETHICON, INC., PELVIC REPAIR	:	CIVIL ACTION NO. 2:12-md-02327
SYSTEM PRODUCTS LIABILITY	:	
LITIGATION	:	MDL No. 2327
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This Document Applies To All Actions	:	Judge Joseph R. Goodwin
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CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2013, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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